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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/406,473	09/27/1999	STEPHEN D. PACETTI	50623-00008	1646
7590 05/04/2005 CAMERON KERRIGAN SQUIRE, SANDERS & DEMPSEY LLP ONE MARTINE PLAZA SUITE 300 SAN FRANCISCO, CA 94111-3492			EXAMINER THANH, LOAN H	
			ART UNIT 3763	PAPER NUMBER

DATE MAILED: 05/04/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/406,473

Applicant(s)

PACETTI, STEPHEN D.

Examiner

LoAn H. Thanh

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE ____ MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) ____ is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

Election/Restrictions

Applicant's election without traverse of Group I (sheath) , species A (fig.2a) and subspecies A (material of polyurethane having non-polar soft segment and 3/ therapeutic substance contacting surface) in the reply filed on 07/20/04 is acknowledged. Applicant is reminded that the election is toward the sheath and some of his claims are broader than the sheath.

Response to Amendment

The claim objection and the rejection under 35 USC 112, 2nd paragraph have been withdrawn in view of applicant's amendment filed 2/14/05.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 139-142, 144-150 are rejected under 35 U.S.C. 102(b) as being anticipated by Sahatjian et al. (U.S. Patent No. 5,674,192).

Sahatjian et al. disclose a medical kit comprising a coated stent deployed by a balloon catheter wherein the stent is coated with a therapeutic substance . Further, it is disclosed that the sheath is made of polyurethane or TEFLON (fluorinated polymer). Sahatjian et al. teach the sheath is for protecting the drug/coating and for inhibiting

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premature release of the drug. The protective sheath is for preventing the release of the drug prior to reaching the desired location in the body. See col. 1-3, 8, 10-11, and 14. The Examiner is taking the position that it is inherent that the polyurethane has a glass transition temperature (T_g) that is above storage temperature. In the broadest interpretation the storage temperature has not been specified, thus the temperature can be any temperature. Further, it would be inherent for the T_g to be above storage temperature since the sheath would be a solid structure. If the T_g were below the storage temperature then the sheath would be a liquid or unstable form during storage.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 143, 151-154 are rejected under 35 U.S.C. 103(a) as obvious over Sahatjian et al. (U.S. Patent No. 5,674,192).

Sahatjian et al. disclose the invention substantially as claimed. However, Sahatjian et al. does not disclose the non-polar soft segment to be hydrocarbons or silicones or fluorosilicons or mixtures thereof. It is common knowledge in the chemical art to modify the non-polar segments in order to provide properties such as flexibility and bendability which are desired in the medical arts. In absence of convincing

objective evidence to the contrary, it would have been obvious to modify any medically acceptable material to the essential properties, which are desired.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the materials, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

Further, applicant's specification has disclosed suitable combinations of barrier polymers and therapeutic substances but has also disclosed that other suitable combinations are possible. Applicant has also disclosed that in the broader aspects of the invention the sheath may not be in contact with the therapeutic agent and thus the therapeutic substance would not absorb or diffuse into the sheath material.

Applicant is suggested to show or provide criticality or unexpected results of the claimed properties of these materials.

Response to Arguments

Applicant's arguments filed 02/14/05 have been fully considered but they are not persuasive. Applicant's arguments are not convincing. Applicant has not claimed any structural distinguishing features. Although applicant appears to be explaining and arguing his invention, applicant has not claimed his device to distinguish over the prior art of record. Applicant's claims are very broad. Applicant is suggested to amend the claims to distinguish over the prior art with structural distinguishing features and not with properties. It is correct that the Examiner is to consider the specification in

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understanding the claims but the specification is not read into the claims when examining the claims. Applicant should amend the claims with the language and disclosure of the specification into the claims if applicant is relying on distinguishing features from the specification. Applicant appears to be arguing more narrow than claimed. If applicant is not picking "any " temperature then applicant should put that critical temperature into the claim. Applicant appears to be arguing how the device is made and the claims are directed to the device itself. It is well known in the art to manipulate temperature and processes involved in the making of a device to obtain "new" or modified materials. Basically, the general skilled worker in the art of polymers knows how to manipulate a material to obtain certain properties. Further applicant is arguing more narrow than claimed with respect to the "rigid". "rigid has not been claimed. Besides, the device has some rigidity. With respect to applicant's arguments on the bottom of page 9, the known material is polyurethane. The material is known as the prior art shows the material used in the food industry.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LoAn H. Thanh whose telephone number is (571) 272-4966. The examiner can normally be reached on Mon. - Fri. (First Friday off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nick Lucchesi can be reached on (571) 272-4977. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read 'LoAn H. Thanh', is positioned above the printed name and title.

LoAn H. Thanh
Primary Examiner
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